Food and Drug Administration
Rockville MD 20857

SEP 27 1996

Re: Neutrexin™
Docket No. 94E-0099

#19

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,376,858, filed by Warner-Lambert Company, under 35 U.S.C. § 156 et seq. The Food and Drug Administration (FDA) is correcting the notice of its determination of the regulatory review period for purposes of patent extension for Neutrexin™ (trimetrexate glucuronate) that appeared in the Federal Register of August 30, 1994 (page 44,737). The notice stated:

> FDA has determined that the applicable regulatory review period for Neutrexin™ is 2,251 days. Of this time, 1,934 days occurred during the testing phase of the regulatory review period, while 317 days occurred during the approval phase. These periods of time were derived from the following dates:
>
> 1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 21, 1987.
>
> The applicant claims September 2, 1987, as the date the investigational new drug application (IND) for Neutrexin™ (IND 29,796) became effective. However, IND 29,796 was placed on clinical hold on March 30, 1987, within 30 days of being received by the agency on March 10, 1987. FDA records indicate that the IND effective date was October 21, 1987, the date IND 29,796 was removed from clinical hold.
>
> 2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: February 4, 1993.

The applicant claims February 1, 1993, as the date the new drug application (NDA) for Neutrexin™ (NDA 20-326) was initially submitted. However, FDA records indicate that the NDA was submitted on February 4, 1993.

It should have stated:

FDA has determined that the applicable regulatory review period for Neutrexin™ is 2,251 days. Of this time, 1,931 days occurred during the testing phase of the regulatory review period, while 320 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 21, 1987.

   The applicant claims September 2, 1987, as the date the investigational new drug application (IND) for Neutrexin™ (IND 29,796) became effective. IND 29,796 was placed on clinical hold on March 30, 1987, within 30 days of being received by the agency on March 10, 1987. The applicant has documentation to suggest that an FDA official orally stated that FDA had removed IND 29,796 from clinical hold on September 2, 1987. However, FDA records indicate that the IND effective date was October 21, 1987, the date IND 29,796 was removed from clinical hold via letter.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: February 1, 1993.

   FDA has verified the applicant's claim that the new drug application (NDA) for Neutrexin™ (NDA 20-326) was initially submitted on February 1, 1993.

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Francis J. Tinney
Patent Department
Warner-Lambert Company
2800 Plymouth Road
Ann Arbor, Michigan 48105